

## REMARKS

This Amendment is responsive to the Office Action of November 6, 2008. Applicant has amended Claims 1, 7 and 19, canceled Claims 6 and 10, such that Claims 1, 5, 7, 15, 15, and 19-21 are pending.

The Prior Action indicated that there was allowable subject matter in Claims 10, 13, 15, and 19-21. The current Action, however, withdraws these indications of in view of the newly discovered reference to Hart et al. In particular, Claims 1, 5 and 7 are now rejected as obvious over Toy et al. in view of Trott and further in view of newly-cited Hart et al., and previously allowed Claims 13, 15, and 19-21 are now rejected as obvious over Toy et al. in view of Trott. Applicant respectfully traverses based on the above amendments and following remarks.

### Claims 1 (now 28) and 7

In order to more clearly present the claimed invention, Applicant has substituted new Claim 28 for Claim 1. Claim 28 is directed to a unique surgical device that comprises a handle assembly, a hollow elongate shaft, an actuating rod, and a needle assembly that moves back and forth between an extended state and a retracted state. Claim 28 is largely directed to the unique structure of the needle assembly, namely a needle assembly comprising:

bifurcated portions of the needle assembly defining a suture slot with a proximal end and a distal end, the bifurcated portions including a backing arm and a gathering arm that are integral with one another at the proximal end of the suture slot, the backing arm and gathering arm having a proximate but spaced relationship when the needle assembly is in the retracted state and having a separated and further spaced relationship when the needle assembly is in the extended state, the backing arm and gathering arm being biased to the separated relationship;

a sharp needle tip formed at a distal end of the backing arm;  
a small portion extending proximally from the sharp needle tip to form a hook around an opening at a distal end of the suture slot to retain

the suture, a portion of the opening remaining distally of the elongate shaft when the needle assembly is in the retracted state;

a distal end of the gathering arm aligning with the proximally extending portion at a position that is closer to the distal end of the suture slot than the proximal end of the suture slot, and

bends in the gathering arm causing the distal end of the gathering arm to extend away from the backing arm to define a wide passage into the suture slot when the needle assembly is in the extended state and the backing arm and gathering arm have the separated relationship, causing the distal end of the gathering arm to extend toward and contact the backing arm when the needle assembly is in a partially retracted position, and causing the distal end of the gathering arm to substantially align with the small portion extending from the sharp needle tip when the needle assembly is in the retracted state.

A preferred embodiment of claimed needle assembly is shown in Figures 11-14 that are reproduced below in the order 14, 13, 12, 11, 12, 13, and 14 in order to illustrate the claimed structure as the needle assembly is moved from a retracted state, to an extended state, and back to a retracted state.

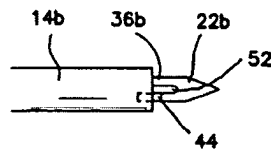


FIG. 14

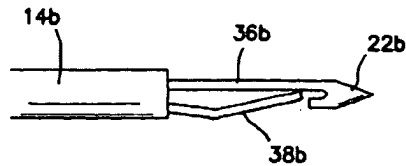


FIG. 13

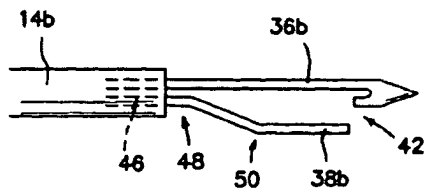


FIG. 12

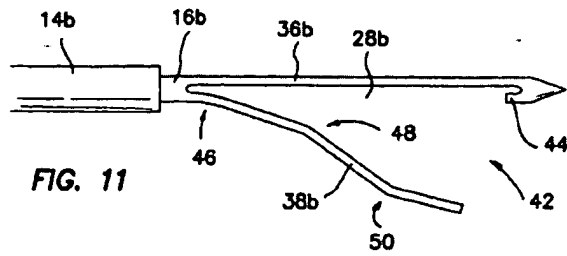


FIG. 11

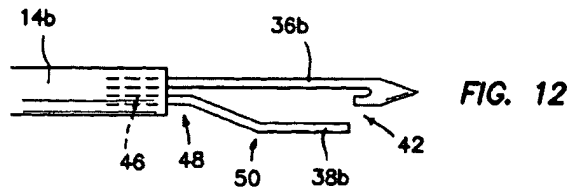


FIG. 12

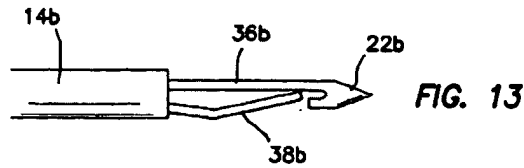


FIG. 13

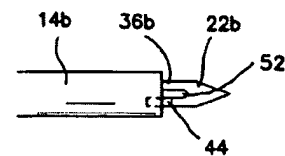


FIG. 14

As shown in the first occurrence of Figure 14, "the backing arm and gathering arm having a proximate but spaced relationship when the needle assembly is in the retracted state."

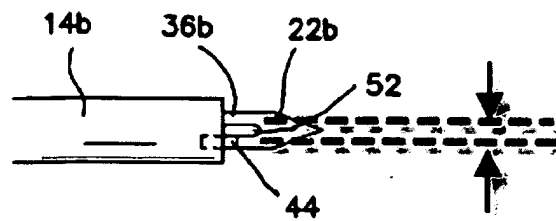
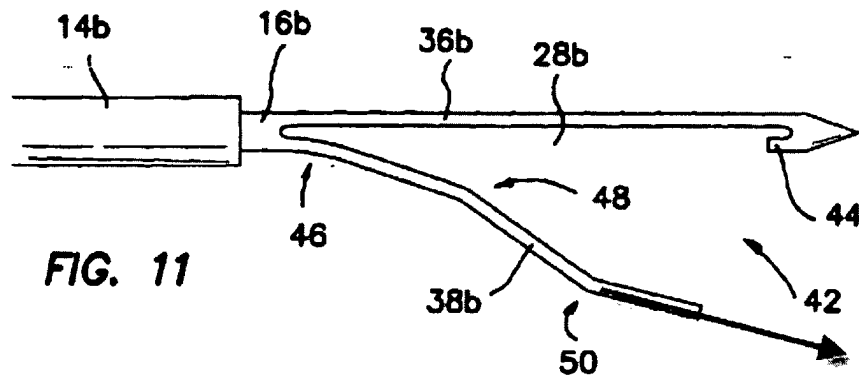
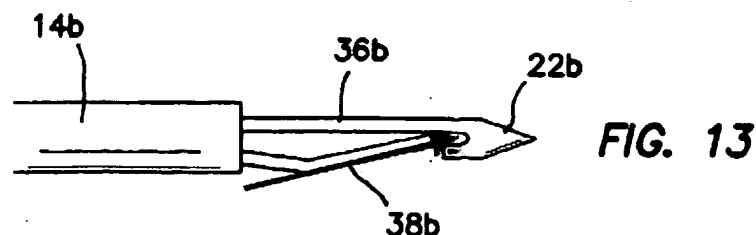


FIG. 14

In addition, as shown in Figure 11, there are “bends in the gathering arm causing the distal end of the gathering arm to extend away from the backing arm to define a wide passage into the suture slot when the needle assembly is in the extended state and the backing arm and gathering arm have the separated relationship...” This unique arrangement helps the surgeon locate the needle assembly over the suture with relatively little difficulty.

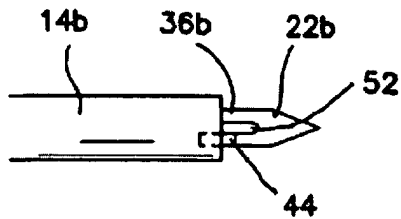


And, of further significance and as shown in the second occurrence of Figure 13, there are “bends in the gathering arm ... causing the distal end of the gathering arm to extend toward and contact the backing arm when the needle assembly is in a partially retracted position. This unique arrangement helps the surgeon *gather* the suture against the backing arm before the needle assembly is fully retracted, i.e. when the needle assembly is in the position shown in Figure 13.



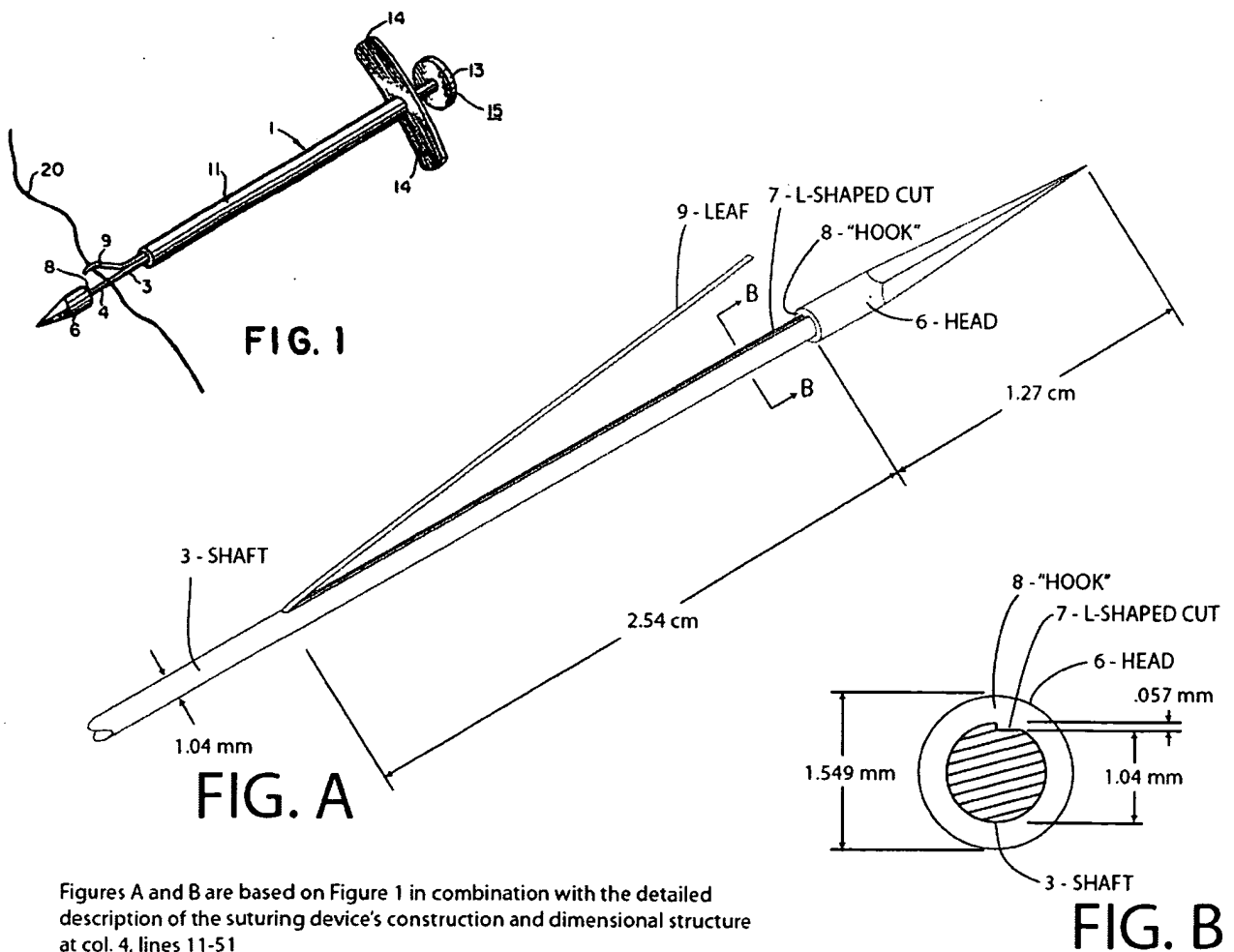
And, lastly, there are “bends in the gathering arm ... causing the distal end of the gathering arm to substantially align with the small portion extending from the

sharp needle tip when the needle assembly is in the retracted state.” This unique arrangement allows the suture to be captured in a suture sliding position.



**FIG. 14**

Toy et al., the base reference in the cited trilogy, discloses a thumb-actuated suturing device that is constructed as follows:



Figures A and B are based on Figure 1 in combination with the detailed description of the suturing device's construction and dimensional structure at col. 4, lines 11-51

**FIG. B**

The Toy device pinches the suture between the "leaf" 9 and the shaft 3 and/or the underside of the head 6. Toy et al. do not teach or suggest that their "leaf" 9 does or should have "a proximate but spaced relationship when the needle assembly is in the retracted state." In fact, it is clear that Toy et al.'s "leaf" 9 will press tightly against the shaft 3 when their needle assembly is retracted into the hollow shaft 11.

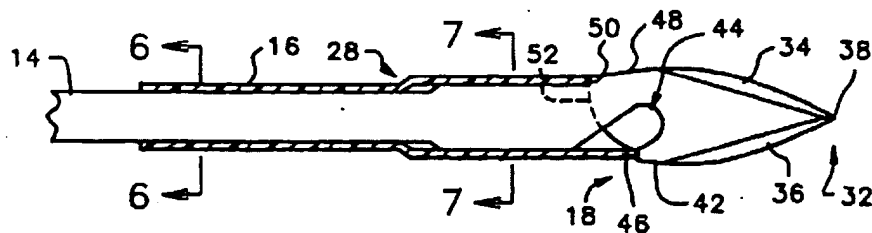
Also, while Toy discloses a shoulder that it calls a "hook," it is clear that Toy et al. does not teach or suggest the bolded part of the following claim element:

**a small portion extending proximally from the sharp needle tip to form a hook around an opening at a distal end of the suture slot to retain the suture, a portion of the opening remaining distally of the elongate shaft when the needle assembly is in the retracted state**

Finally, Toy et al. does not teach or suggest the bolded language at the end of the same claim element:

**a small portion extending proximally from the sharp needle tip to form a hook around an opening at a distal end of the suture slot to retain the suture, a portion of the opening remaining distally of the elongate shaft when the needle assembly is in the retracted state;**

The Office Action concedes that Toy does not disclose the invention as claimed, but suggest that Trott discloses a portion extending from a sharp distal tip to form a hook:



Applicant respectfully submits that one of ordinary skill in the art would not be motivated to modify Toy to include an actual hook and notch as taught by Trott because the devices function in entirely different ways. Toy specifically teaches that its

device "clamps the suture between the end of the sheath 11 and the underside of the head 6." Adding a hook and notch to Toy would entirely eliminate this clamping functionality.

Moreover, even if one were to assume that a person of ordinary skill in the art would modify Toy to have a Trott-like hook, there is no teaching in Trott that would cause such a person to go against Toy's grain and provide for a "proximate but spaced" relationship between a gathering arm and a backing arm.

Finally, there is nothing in Toy to teach or suggest the claimed bends corresponding functionality that is described above relative to the preferred embodiment of Figures 11-14 and set forth in claim 28.

The Office Action also notes that neither Toy nor Trott discloses an "inward bend" that causes the gathering arm to contact the backing arm (language in prior claim 1), and then looks to Hart as allegedly disclosing such an inward bend in its Figure 63 and related description.

Applicant respectfully submits that Hart is so entirely different than either Toy or Trott that it is inappropriate to combine them. Toy and Trott both disclose a hollow shafts and a reciprocating needle assembly where the sharp needle tip is part of the reciprocating needle assembly and not part of the hollow shaft. Hart, by contrast, disclose a hollow shaft with a sharp tip and a pair of wire-like elements inside of that shaft:

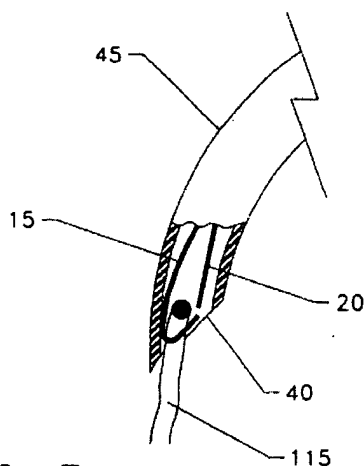


FIG. 7

Applicant also respectfully submits that Hart's wire-like elements are very much unlike the needle assemblies in Toy or Trott in that the elements are, first off, wire-like, and second off, are connected to a reciprocating rod way back in the device's handle:

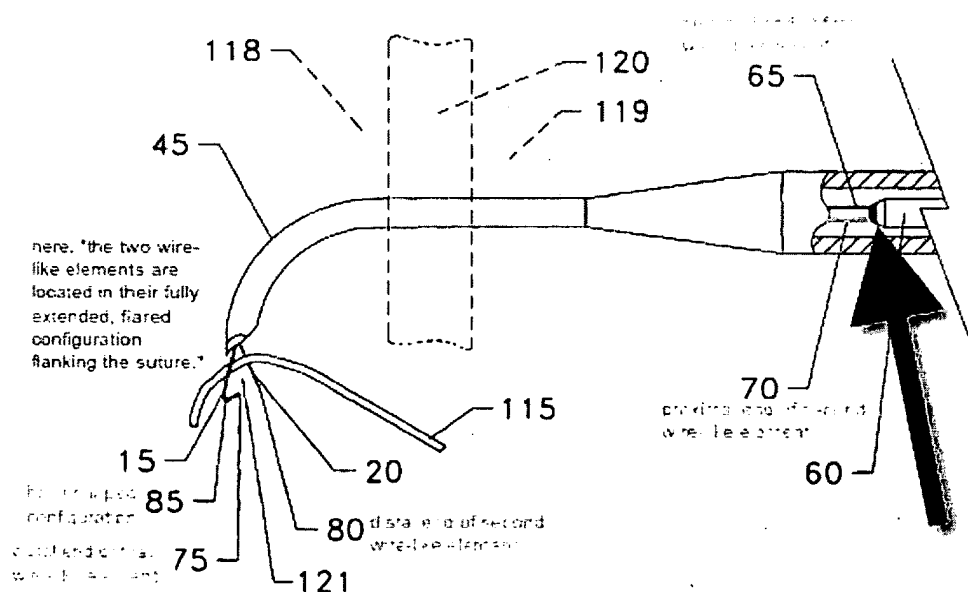


FIG. 4

Applicant respectfully submits that the Office Action appears to be misinterpreting Hart's Figure 63, reproduced here:



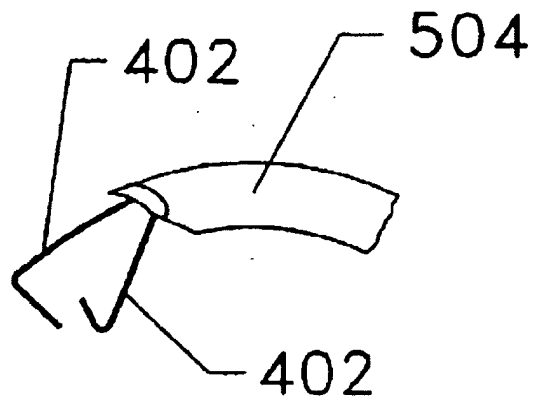
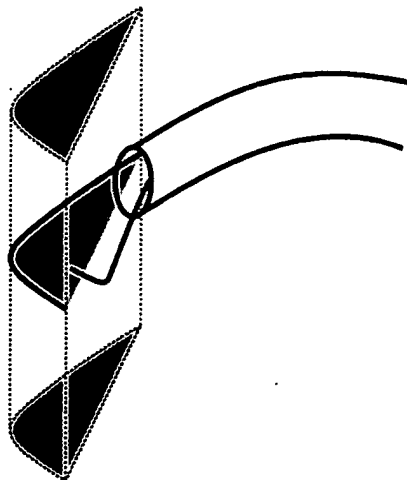


FIG. 63

According to the description at Col. 15, line 66, to Col. 16, line 5, Figure 63 shows how the wire-like elements may each have a hook at their distal ends and, more specifically, “the hook of one wire-like element resides **within a projection of the area enclosed by the hook of the other wire-like element** during closure.” (emphasis added). The foregoing language means that if one were to take the triangular area enclosed by the left-most element 402, the right-most element 402 would reside within a three-dimensional projection of that triangular area during closure:



The Office Action says, "Apparently, the advantage is providing a positive capturing means for the surgeon to capture suture and secure the suture before the needle is completely in the full retracted position." (emphasis added). Applicant respectfully submits that this conclusion is not apparent from Figure 63 and the related description. Hart simply says that the right-most element will move into the triangular projection of the triangular area of the other element, but there is no reason to believe that the right element will press against the left wire-like element. The two elements will likely be moving in different planes and will thus pass one another like the arms of a child making a bad catch.

Claim 28, by contrast, specifically requires that there are "bends in the gathering arm ... causing the distal end of the gathering arm to extend toward and contact the backing arm when the needle assembly is in a partially retracted position."

Based on the foregoing, Applicant respectfully submits that Claim 28 is allowable over the prior art of record and that dependent Claim 7 is allowable at least by virtue of its dependence from Claim 28.

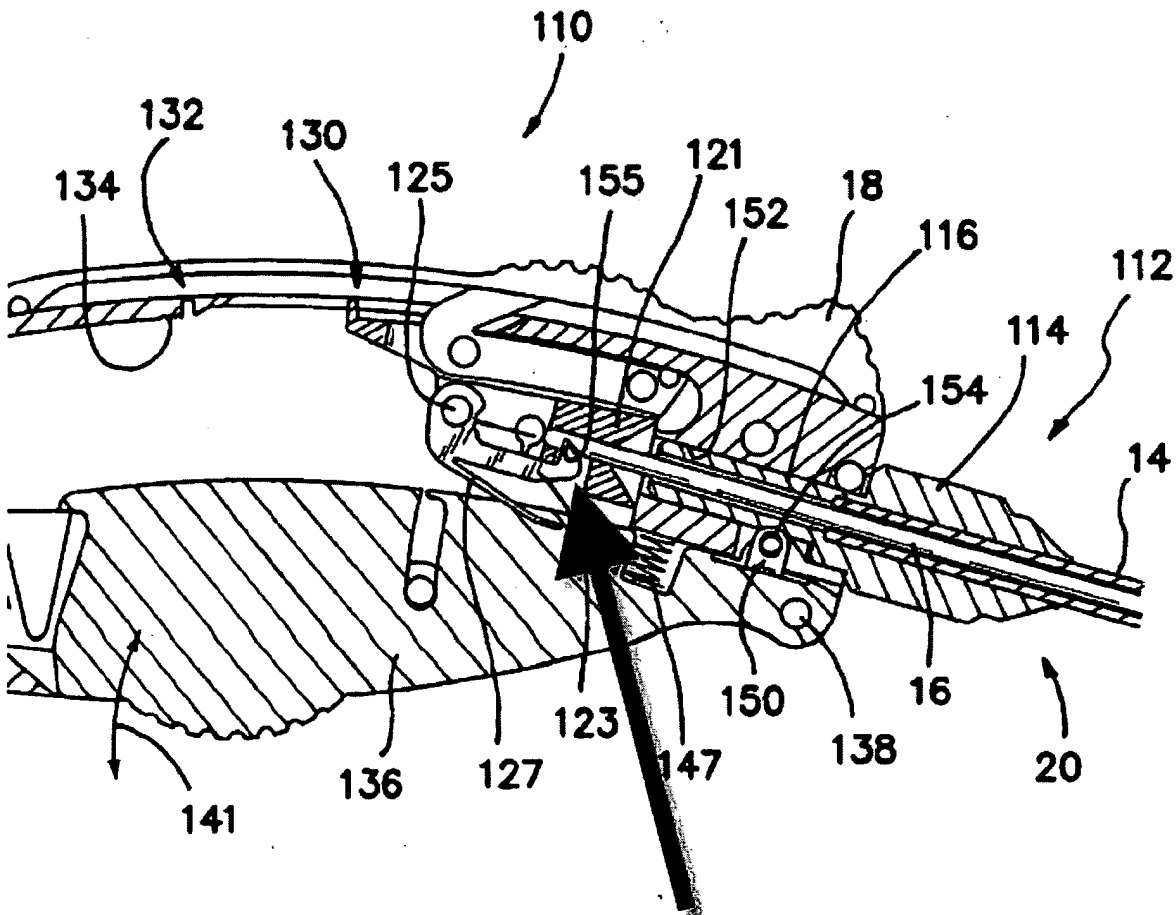
#### **Claims 13, 15, and 19-21**

Claims 13, 15, and 19-21 were previously allowed, but now stand rejected over Toy in view of Trott after further review. It appears that the Office Action is correlating Trott's "positive lock assembly L" with the claimed structure. Applicant respectfully traverses.

Claim 13 requires a needle and a needle housing. More particularly, Claim 13 recites "a needle assembly having a needle moving in a needle housing

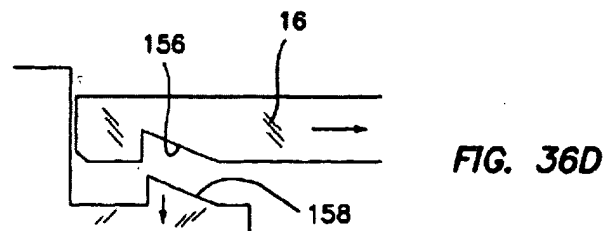
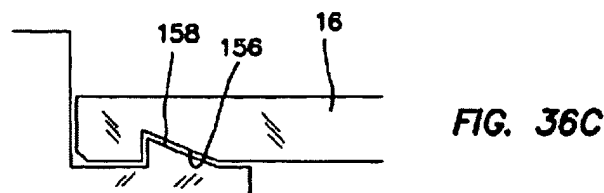
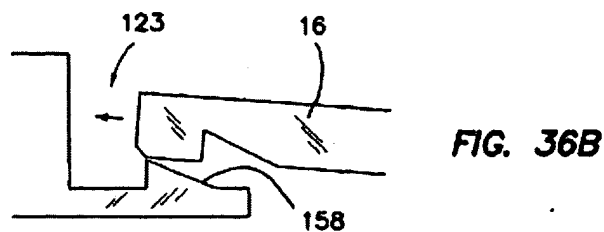
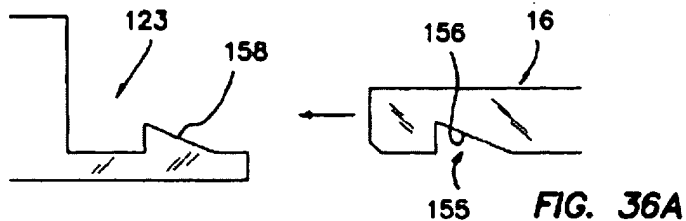
between a free suture state, a capture suture state, and a locked suture state.” The claim further requires “a thumb slide assembly reliably coupled to the needle...” and, unlike Toy or Trott, “a needle latch included in the thumb slide assembly and having a releasable latching relationship with the needle”.

In the preferred embodiment of Figure 35, there is a thumb slide assembly 18 and a needle assembly 20 that includes a needle 16 moving inside of a needle housing 14. The preferred embodiment further comprises a needle latch 123 that has a releasable latching relationship with the needle.



**FIG. 35**

Figures 36A to 36D illustrate one embodiment of the claimed "latching relationship":



Applicant acknowledges that Trott's needle terminates in a loop 56 having an angled extension member 58 that engages a detent 64 in the handle until the user applies sufficient pressure against the thumb slide. However, this relates only to locking the thumb slide in a captured suture state, not to a latching relationship between the thumb slide and the needle. Trott does not disclose "a needle latch included in the

thumb slide assembly and having a releasable latching relationship with the needle” as required by amended Claim 13.

Applicant has amended the terminology from “needle lock” to “needle latch” to be consistent with the original specification (see e.g. paragraph [0104]) and, as illustrated above in the context of the preferred embodiment, to show that such an element is not found in or suggested by Trott.

Claim 13 also features “a needle housing lock carried by the handle housing and having a releasable locking relationship with the needle housing”. In Trott, by contrast, the only structure analogous to the claimed needle housing is Trott’s inner and outer tubes 16, 20 and those tubes are conjoined with the handle 2. To put it the other way, they are not releasably locked to the handle 2.

Based on the foregoing, Applicant respectfully submits that Claims 13, 15, and 19-21 are again in condition for allowance.

### **Summary**

Based on the attached amendments and accompanying remarks, Applicant respectfully submits that the pending Claims are in patentable condition and earnestly solicits a timely Notice of Allowance. Applicant encourages the Examiner to telephone the undersigned attorney if it appears that a telephone conference would further this case in any way.

Respectfully submitted,

/s/ - signed May 6, 2009

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